JUL - 7 2000

K001320

510(k) SUMMARY

Submitter: Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, TX 78717
Tel: (512) 432-9900
Fax: (512) 432-9291

Contact: Frances E. Harrison
Senior Regulatory Affairs Specialist

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.353).

Common/Usual Name: Total Hip Prosthesis

Trade/Proprietary Name: Natural-Hip™ System LD Stem

Product Description:

The Natural-Hip System LD Stems are straight stems employing Sulzer 12/14 configured neck trunnions permitting attachment to either metallic heads having a Sulzer 12/14 configured bore. They are available with or without a proximal collar. The stems are designed with a widened proximal geometry to fill the metaphyseal cavity of the femur. Moreover, the distal portion employs a hole for the attachment of a polymethylmethacrylate distal centralizer.

The Natural-Hip System LD Stems may be manufactured from forged cobalt chrome alloy (CoCr, ASTM F799 or ISO 5832-12), wrought CoCr alloy (ASTM F1537) or cast cobalt chromium alloy(ASTM F-75-92). Additionally, the surface of the stem is grit blasted for enhanced fixation in both cemented and cementless (press fit) applications.

The Natural-Hip System LD Stems are available in sizes 0-6.

Intended Use/Indications for Use:

The Natural-Hip LD Stem is intended for cemented or cementless use to replace the anatomy of the femur in cases of total hip or hemi-hip replacement. It is intended to be used with Sulzer Orthopedics acetabular components and femoral head components having a 12/14 taper.

The general indications associated with the use of the Natural-Hip LD Stem include:

- patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- those patients with failed previous surgery where pain, deformity or dysfunction persists.
- revision of previous failed arthroplasty.

Substantial Equivalence:

The Natural-Hip System LD Stems are substantially equivalent to the previously cleared Natural-Hip System LD Stems as they have the same intended use, indications for use, design, materials, sterilization and method of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Frances E. Harrison
Senior Regulatory Affairs Specialist
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K001320
Trade Name: Natural-Hip™ System LD Stem
Regulatory Class: II
Product Code: LPH
Dated: April 25, 2000
Received: April 26, 2000

Dear Ms. Harrison:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bachner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001320

Device Name: Sulzer Orthopedics Inc. Natural-Hip™ System LD Stem

Indications For Use:

The Natural-Hip System LD Stem is intended for cemented or cementless use to replace the anatomy of the femur in cases of total hip or hemi-hip replacement.

The general indications associated with the use of the Natural-Hip System LD Stem include:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity or dysfunction persists.

3. Revision of previously failed arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of General Rest[illegible]ive Devices
510(k) Number K001320

Prescription Use Yes OR Over-The-Counter Use No

(Optional Format 1-2-96)